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No. 09-335

In the
Supreme Court of the United States

ASTELLAS PHARMA, INC.

Petitioner,

v.

LUPIN LIMITED, LUPIN PHARMACEUTICALS, INC., TEVA PHARMACEUTICALS USA, INC., TEVA PHARMACEUTICAL INDUSTRIES, LTD., and SANDOZ INC.

Respondents.

On Petition For A Writ Of Certiorari To The United States Court Of Appeals For The Federal Circuit

REPLY BRIEF IN SUPPORT OF PETITION FOR A WRIT OF CERTIORARI

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RULE 29.6 STATEMENT

As required by the Court's Rule 29.6, Astellas Pharma, Inc. states that there is no parent corporation and no publicly held company owns 10% or more of its stock.

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REPLY IN SUPPORT OF PETITION FOR *CERTIORARI*

Respondents do not contest that under the Court's binding precedent: "That which infringes, if later, would anticipate, if earlier."[1] *Peters v. Active Mfg. Co.*, 129 U.S. 530, 537 (U.S. 1889) (internal quotations omitted). Respondents' concession is fatal to their argument that the *en banc* decision below does not contradict the Court's precedent. Two of the respondents argue, however, that the Federal Circuit took the unprecedented step of *sua sponte* issuing an *en banc* opinion over vigorous dissents merely so it could provide unnecessary *dicta*. But those respondents are incorrect, and the Court should grant the petition for *certiorari*.

Petitioner's main argument is that the *en banc* holding violates the Court's precedent because "claims are now interpreted differently for validity purposes than for infringement purposes." Pet. at 11. Lupin argues, however, that the claims are interpreted the same for infringement and validity because if "a company...produced Crystal A *by the*

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[1] The Respondents are: Lupin Limited and Lupin Pharmaceuticals, Inc. (collectively, "Lupin"), Teva Pharmaceuticals USA, Inc. and Teva Pharmaceutical Industries, Ltd. (collectively, "Teva"), and Sandoz Inc. ("Sandoz"). Although Teva and Sandoz are not parties to the Federal Circuit's decision in 2007-1446 (this case), they were appellees in the companion case 2007-1400 (which denied Astellas's request for a preliminary injunction), and they have submitted their briefs under Supreme Court Rule 12.6. Although Astellas is not seeking review of the denial of its motion for a preliminary injunction, Astellas has attached that order to this reply for the Court's convenience.

process described in the '507 patent before that patent's priority date, the invention would have anticipated petitioner's patent claim; and the same product produced by that same process would infringe...if practiced later." Lupin Opp. at 24 (emphasis added). But Lupin's argument does not address Petitioner's argument that, under the Federal Circuit's new rule, the product made by a *different* process anticipates if earlier but does *not* infringe if later. Pet. at 13.

Moreover, any doubt that the *en banc* holding requires different interpretations for infringement and validity has been erased by *Amgen Inc. v. F. Hoffmann-La Roche, Ltd.*, 580 F.3d 1340 (Fed. Cir. 2009).[2] *Amgen* held that "*[f]or product-by-process claims, that which anticipates if earlier does not necessarily infringe if later.* That is because a product in the prior art made by *a different process can anticipate* a product-by-process claim, but an accused product made by *a different process cannot infringe* a product-by-process claim." *Id.* at 1370 (emphasis added). Thus, the Federal Circuit has now turned product-*by*-process claims into product claims for validity purposes and into product-*and*-process claims for infringement purposes.

Teva argues, however, that the Court should ignore *Amgen* because "[t]o the extent that the *Amgen* panel decision conflicts with...*Atlantic Thermoplastics*...[a]ny intra-circuit divergence should be addressed first *en banc* by the Federal

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[2] *Amgen* issued the day Astellas sent its petition to the printer.

Circuit."[3] Teva Opp. at 10. Teva's argument is both wrong and irrelevant. It is wrong because there is no conflict, as *Atlantic* held that "product-by-process claims are limited by and defined by the *process* [for infringement], determination of patentability [validity] is based on the *product* itself." *Atlantic Thermoplastics Co., Inc. v. Faytex Corp.*, 970 F.2d 834, 845 (Fed. Cir. 1992) (emphasis added). Thus, like *Amgen*, *Atlantic* also held that product-by-process claims are interpreted differently for infringement and validity.[4]

Teva's argument is irrelevant because any split was resolved by the *en banc* decision here. *Amgen* was merely following the *en banc* decision as it must. *See Amgen*, 580 F.3d at 1370 (citing to the *en banc* decision). Therefore, the only way to prevent the Federal Circuit's binding *en banc* holding (which requires different claim interpretations for validity and infringement) from improperly overruling *Peters* is for the Court to grant the petition.

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[3] Contrary to Teva's implication, *see* Teva Opp. at 10 n.5, only one member of the unanimous *Amgen* panel dissented from the *en banc* decision.

[4] Teva points to the following dicta in an attempt to gin up a conflict: "In any event, claims mean the same for infringement and validity." *Atlantic*, 970 F.2d at 846. But that quote comes immediately after *Atlantic* demonstrated that it does treat claims differently for "infringement and validity," which is why the quote begins, "In any event." The fact that *Atlantic* tried to make its improper overruling of *Scripps* more palatable by downplaying the significance of its holding cannot change the fact that its holding was a dramatic change in the law.

Lupin argues, however, that "any asymmetry" between how claims are interpreted for infringement versus validity "has been accepted by this Court for more than a century." Lupin Opp. at 26. It bases this argument on its contention that the dissent "did not dispute that the disparity necessarily arises under what it conceded was the 'general rule' described in cases like *BASF*." Lupin Opp. at 26 (*citing* Pet. App at 45, 54). But Lupin provides no support for its incredible claim that this Court "accepts" lower courts ignoring the Court's binding precedent. Moreover, Lupin's characterization of the "general rule" is wrong. "[T]he general rule [is] that new products are claimed without reference to the process by which they are produced." Pet. App. at 45. Product-by-process claims are then an exception to the "general rule" because the process *describes* the product claimed for both validity and infringement purposes. Accordingly, the "asymmetry" that the Court allegedly "accepts" only came about now, where the *en banc* majority has chosen to treat the process as a *description* of the product claimed for validity purposes but as a *limitation* on the product claimed for infringement purposes. The Court should not "accept" this disregard of its precedent and grant the petition for *certiorari*.

Lupin and Sandoz next attempt to change the subject, arguing that the Federal Circuit went *en banc* to issue meaningless *dicta* that has "no effect on the outcome of this litigation." Lupin Opp. at 10; *accord* Sandoz Opp. at 8. Their argument is based on their incorrect claim that it is an established fact

that their products contain only Crystal B and not Crystal A.

Regarding Sandoz, the Federal Circuit correctly noted that "the parties to the *Sandoz* litigation disputed whether Sandoz and Teva's products also contained small amounts of...Crystal A."[5] Pet. App. 34. The Federal Circuit upheld the district court's denial of a preliminary injunction, however, because Astellas, as the moving party, had not proven at the preliminary injunction stage that Sandoz's product contains Crystal A. *Id.* at 36. But that factual issue has not been resolved.

Similarly, regarding the Lupin products, Lupin alleges that its cefdinir is "composed *almost* entirely of Crystal B." Lupin Opp. at 4 (emphasis added). Assuming *arguendo* that statement is true, it still leaves open whether Lupin's products also contain Crystal A. The Federal Circuit held that it need not decide that issue because Astellas had conceded that it had not proven that Lupin practiced the processes described in claims 2-5. Pet. App. at 30. Accordingly, Lupin is wrong when it claims that "[t]he question in this case is whether respondent's use of Crystal B violates the petitioner's patent." Lupin Opp. at 1. Rather, the question in this case is whether Lupin's products contain Crystal A, in addition to Crystal B.[6] Thus, if the Court reverses

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[5] This quote demonstrates that Teva was correct in not joining Sandoz's argument that the *en banc* decision is meaningless dicta.

[6] Lupin incorrectly claims that Astellas abandoned its "theory" that Lupin's products "contained material amounts of Crystal

the Federal Circuit and holds that process steps are not limitations on product-by-process claims, Astellas will then put forth evidence demonstrating that Lupin's products *do* contain Crystal A.

Respondents misunderstand the remainder of Petitioner's arguments. For example, Petitioner explained in its opening brief that the *en banc* decision was wrong because it necessarily led to the panel having to redefine the term "obtainable by" to be "obtained by." Pet. at 28-29. As *Respondents* explained, "it is a fundamental tenet of patent law that the wording of the claims determines the scope of the patent." Sandoz Opp. at 5. But the only way to read the process into the claim as a limitation is to ignore "the wording of the claim" and change "obtainable by" to "obtained by." Thus, Petitioner

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A" because Astellas withdrew its claim for literal infringement of claim 1. Lupin Opp. at 4-5 n.3 (*citing* Pet. App. at 93). But Astellas withdrew that claim because of the difficulty of proving that Lupin's products infringed that claim. As Lupin explained, claim 1 "is a traditional product claim which *further* characterizes the product by reference to its unique x-ray fingerprint from a 'powder X-ray diffraction [PXRD] test.'" Lupin Opp. at 3 (emphasis added). Therefore, to prove infringement under Claim 1, Astellas must show all seven PXRD peaks, which are all limitations under that claim. Pet. App. at 5. But when Crystal A and Crystal B are mixed, as they are in the Lupin product, some of the PXRD peaks created by the Crystal B product obscure some of the seven PXRD peaks required by Claim 1. But claims 2 through 5 do not include the limitation that the product is "*further* characterized" by the seven PXRD peaks. *Id.* at 6. Therefore, Astellas chose only to proceed with those claims because it would be easier to prove that Lupin's products contain Crystal A (along with Crystal B) for those claims.

was not asking the Court to grant *certiorari* to correct the panel's interpretation of the term "obtainable by." Rather, Petitioner was demonstrating that the *en banc* holding is incorrect because it requires courts to change the term "obtainable by" to "obtained by," which puts thousands of patents at risk.[7]

Respondents also misinterpret Petitioner's arguments regarding the Federal Circuit's failure to follow its own procedures. Astellas explained that the Federal Circuit was wrong to issue an *en banc* opinion that was affecting thousands of existing patents without informing either the parties or the public that it was considering changing the law on product-by-process claims. Astellas was not asking the Court to grant *certiorari* because the *en banc* majority lacked jurisdiction to take such a course of action, but rather to ameliorate the harm caused by its failure to follow its own procedures.

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[7] Lupin was correct, however, in stating that Astellas overstated the number of existing patents with the phrase "obtainable by" because, when it ran its search, Astellas erroneously also included patent applications. Lupin Opp. at 16 n.9. Astellas regrets its error. But its error does not change the larger point that thousands of issued patents are at risk. In addition, the fact that there have been nearly 1,000 applications published in the last year with that term (compared to 2,600 issued patents in the previous twenty years) demonstrates that the importance of product-by-process patents is increasing. (Astellas found approximately 958 patent applications based on a search of the Lexis "Utility, Design and Plant Patents" database using the search term "obtainable by" in the segment "claims" for patent applications filed between November 27, 2008, and November 26, 2009.)

Respondents argue, however that the *en banc* majority's failure to follow the Federal Circuit's procedures is harmless because 1) this case is not important, and 2) Judge Newman fully advanced Astellas's arguments. *See* Teva Opp. at 12; Sandoz Opp. at 11-12; Lupin Opp. at 16.

Respondents' contention that this case was not important is based on 1) the fact that no *amicus* briefs were filed, and 2) Abbott did not seek *certiorari*. *Id.* First, *amici* typically do not file at the petitioning stage because even if a petition has merit, the odds against the Court granting *certiorari* are high due to the thousands of petitions that are filed each year. Therefore, in the current economic climate, it is not surprising that *amici* might not choose to expend their limited resources until the merits stage of the proceedings. Second, Abbott (a licensee) is in a very different position than Astellas (the patent holder). Once other generic drug companies were able to market crystalline cefdinir, Abbott's market was destroyed. Thus, Abbott chose not to devote further resources to this lawsuit. Accordingly, Abbott's failure to file a petition for *certiorari* is not evidence that this case is unimportant.[8]

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[8] Teva also argues that this case is not important because it alleges that this issue has only arisen "on two previous occasions in the twenty-five year history of the...Federal Circuit." Teva Opp. at 2. That statement is simply not true because this exact issue was raised in *SmithKline Beecham Corp. v. Apotex Corp.*, 439 F.3d 1312, 1318-19 (Fed. Cir. 2006). Moreover, Teva's argument is also undercut by the fact that the Federal Circuit again addressed this issue in *Amgen Inc.*, 580 F.3d at 1370. Finally, Teva's argument is further undercut by

In any event, all of the Respondent's arguments that this case is unimportant cannot overcome one simple fact: The Federal Circuit decision to hear this case *en banc* which is limited to "question[s] of exceptional importance."[9] Fed. R. App. P. 35(a)(2).

While Astellas agrees that Judge Newman's dissenting opinion ably explains why the majority is wrong, it did not advance Astellas's main argument. What was missing from Judge Newman's dissent was that this Court's precedent *requires* the process to *not* be a limitation in a product-by-process claim because "[t]hat which infringes, if later, [must] anticipate, if earlier." *Peters,* 129 U.S. at 537. While Judge Newman did explain that, under Federal Circuit law, the same interpretation must be used for both infringement and validity, Pet. App. at 81-82, the *en banc* court was free to overrule that

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the numerous district court cases that have addressed this issue. In addition, to the cases cited in Petitioner's opening brief, at least the following published cases all addressed this issue: *Aventis Pharms., Inc. v. Barr Labs., Inc.*, 335 F. Supp. 2d 558, 581-82 & n.21 (D.N.J. 2004); *Union Carbide Chems. & Plastics Tech. Corp. v. Shell Oil Co.*, 163 F. Supp. 2d 426, 437 (D. Del. 2001); *AK Steel Corp. v. Sollac*, 234 F. Supp. 2d 711, 739 n.1 (S.D. Ohio 2002); *Lucent Techs., Inc. v. Gateway, Inc.*, 509 F. Supp. 2d 912, 927-28 (S.D. Cal. 2007).

[9] A further example of this case's importance is the fact that that the FDA now allows product-by-process claims to be listed in the Orange Book for new drugs. *See* Pet. at 31-32. As Petitioner explained, "the Federal Circuit's decision here contradicts the FDA's decision." *Id.* None of the Respondents contest this argument.

precedent. But the *en banc* court was not free to overrule *Peters*, which was not mentioned in either of the dissents. Thus, because the main thrust of the majority's opinion was that *this Court's precedent requires* that the process be treated as a limitation, when in actuality *this Court's precedent requires* that the process *not* be treated as a limitation, the majority's decision denying Astellas and the public the opportunity to brief this issue was not harmless.

Lupin next argues that cases from the Court support the opinion below. Lupin Opp. at 18-22. As Judge Newman addressed all of those cases, Astellas will not repeat her analysis here. Astellas notes, however, that it explained in its opening brief that virtually every commentator who addressed this issue found that the majority's interpretation of those cases (and by extension, Lupin's interpretation) was wrong. Pet. at 24-25. Not only does Lupin not address that issue, but Lupin fails to point to a single commentator who agrees with Lupin's reading of those cases. Simply put, all the cases cited by Lupin either address old products or are referencing *dicta* that was not relevant to the decision of the case.

Lupin also argues that the Court should deny the petition because Astellas is arguing for a "novel rule," Lupin Opp. at 3, that is much broader than the "the limited 'rule of necessity' advanced by the dissent below." *Id.* at 17. First, Lupin is wrong because Astellas is not asking for a "novel rule." For at least thirty years, product-by-process claims have not been limited to claims that meet the rule-of-necessity. *See In re Steppan*, 394 F.2d 1013, 1019

(C.C.P.A. 1967) (the rule-of-necessity is not supported by the patent statute); *Recent Cases...The Trustees of Columbia University v. Roche Diagnostics GmbH, 126 F. Supp. 2d 16 (D. Mass. 2000)*, 115 Harv. L. Rev. 923, 924 n.1 (Jan. 2002) (in 1979, the PTO discarded the rule-of-necessity and "now allows inventors to employ product-by-process claims freely").

Second, Lupin is wrong because Astellas is asking for the exact rule put forward by Judge Lourie in his dissent: "When a product is new and the inventor claims it by a process of preparation,...the product-by-process claim should...be interpreted as a product claim that can be infringed even when the product is made by means other than that recited in the claim." Pet. App. 87.

Finally, Lupin argues against product-by-process claims because 1) the product is not "fully disclosed," Lupin Opp. at 27, 2) they claim "an unidentified proxy product," *id.* at 28, and 3) they "unmoor[] patent protection from the disclosures in the patent." *Id.* at 29. But in all three cases, if the product claimed is not fully disclosed, the claim would be invalid for indefiniteness. *See* 35 U.S.C. 112 ¶ 2; Brian S. Tomko, Comment, *Scripps or Atlantic: The Federal Circuit Squares Off Over the Scope of Product-By-Process Patents*, 60 Brooklyn L. Rev., 1693, 1705 (Winter, 1995) (product-by-process claims are proper if "definite"). Lupin also argues that "[u]nder petitioner's view...to determine whether a patent claim is infringed, it would never be enough to simply compare the claims in the

patent with the allegedly infringing product and process." Lupin Opp. at 28. But "[u]nder petitioner's view" (and the rule from *Peters*), proving infringement only involves comparing the product claimed to the alleged infringer's product, without regard to the alleged infringer's process.

CONCLUSION

For the foregoing reasons, along with the reasons stated in Astellas's petition, the petition for *certiorari* should be granted.

Respectfully submitted,

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APPENDIX

Abbott Laboratories, and Astellas Pharma, Inc., Plaintiffs

v.

Sandoz, Inc., Sandoz GmbH, Teva Pharmaceuticals USA, Inc., Teva Pharmaceutical Industries, Ltd., Ranbaxy, Inc., Ranbaxy Laboratories, Ltd., Par Pharmaceutical Companies, Inc., and Par Pharmaceutical, Defendants.

No. 07 C 1721

UNITED STATES DISTRICT COURT FOR THE NORTHERN DISTRICT OF ILLINOIS, EASTERN DIVISION

486 F. Supp. 2d 767

May 3, 2007, Decided
May 3, 2007, Filed

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JUDGES: Wayne R. Andersen, District Judge.

OPINION BY: Wayne R. Andersen

MEMORANDUM OPINION AND ORDER

Before the court is plaintiffs Abbott Laboratories ("Abbott") and Astellas Pharma, Inc.'s ("Astellas") motion for a preliminary injunction. Abbott seeks a preliminary injunction preventing defendants Sandoz, Inc. and Sandoz GmbH ("Sandoz") and defendants Teva Pharmaceutical Industries, Ltd. and Teva Pharmaceuticals USA, Inc. ("Teva") from manufacturing, selling, offering for sale, importing or distributing their respective generic cefdinir products before a decision on the merits in this case.

For the following reasons, the plaintiffs' motion for a preliminary injunction is denied.

BACKGROUND

Cefdinir is an antibiotic which has sales exceeding $ 600 million annually worldwide. In 1983, plaintiff Astellas's corporate predecessor, Fujisawa, developed the compound cefdinir, which treats bacterial infections, and thereafter secured U.S. Patent No. 4,559,334 ("'334 patent"). The '334 patent claimed an amorphous form of cefdinir, which was not useful for making pharmaceutical products because it was difficult to store, unstable, and not appropriately soluble. Astellas then developed a crystalline form of cefdinir, which is practical as a pharmaceutical product, and secured U.S. Patent No. 4,935,507 ("'507 patent") in 1990 on that product. Abbott has the exclusive license for the '507 patent and markets its Omnicef brand cefdinir, a form of crystalline cefdinir sold as two products.

The '334 patent expires on May 6, 2007 at 11:59 p.m., EDT. The '507 patent expires on December 4, 2011. On April 6, 2007, the United States Food and Drug Administration ("FDA") approved defendant Sandoz's Abbreviated New Drug Applications ("ANDA"), Nos. 06-5330 and 06-5337, to market and sell generic cefdinir products. Defendant Teva filed its ANDAs on June 29, 2005 and November 1, 2005 (Nos. 65-332 and 65-368), but the FDA has not yet approved them.

The parties agree that Abbott's '334 patent expiration permits generic products to launch if those new products do not infringe on the '507 patent. The

'507 patent is a crystalline form of cefdinir, namely, cefdinir anhydrate, called "Crystal A" in the '507 patent. Plaintiffs contend that the defendants' generic products, which the parties agree are cefdinir monohydrate, infringe the '507 patent because cefdinir monohydrate is contained within the claims of the '507 patent, and also because the defendants' generic products may contain a small percentage of cefdinir anhydrate (allegedly approximately 2% for Teva, and approximately .2% for Sandoz). Defendants claim that their competing products do not infringe because cefdinir monohydrate is not covered by the claims in the '507 patent and deny that their products contain any cefdinir anhydrate at all.

DISCUSSION

In order to prevail on a motion for preliminary injunction, plaintiffs must show (1) a reasonable likelihood of success on the merits; (2) irreparable harm if an injunction is not granted; (3) a balance of hardships tipping in its favor; and (4) the injunction's favorable impact on the public interest. *Amazon.com, Inc. v. Barnesandnoble.com, Inc.*, 239 F.3d 1343, 1350 (Fed. Cir. 2001); *Reebok Int'l Ltd. v. J. Baker, Inc.*, 32 F.3d 1552, 1555 (Fed. Cir.1994). Plaintiff has the burden of proving each of these factors. *Roland v. Air Line Employees Ass'n, Int'l*, 753 F.2d 1385, 1392 (7th Cir. 1985).

Because the present case arises under United States patent law, the Patent Act grants authority to this court to grant or deny an injunction to prevent the infringement of a patent.

> The several courts having jurisdiction of cases under this title may grant injunctions in accordance with the principles of equity to prevent the violation of any right secured by patent, on such terms as the court deems reasonable.

35 U.S.C. § 283. We begin our discussion by examining each of the required elements for a preliminary injunction.

The first element of a motion for preliminary injunction is to determine whether the moving party likely will succeed on the merits of the underlying litigation. In patent cases, the movant has an added burden. Here, plaintiffs must show that (1) they will likely prove that defendants infringed the '507 patent, and (2) their infringement claim will likely withstand defendants' challenges to the validity and enforceability of the '507 patent. See *Abbott Labs. v. Andrx Pharms., Inc.*, 452 F.3d 1331, 1335 (Fed. Cir. 2006). "In other words, if [defendants] raise a 'substantial question' concerning validity, enforceability, or infringement (i.e. assert a defense that [plaintiff] cannot show 'lacks substantial merit') the preliminary injunction should not issue." *Id.*, quoting *Genentech, Inc. v. Novo Nordisk, A/S*, 108 F.3d 1361, 1364 (Fed. Cir. 1997).

In order to assess the likelihood of infringement, the court must (1) first determine, as a matter of law, the correct meaning and scope of the asserted claims, and then (2) compare the properly construed claims to the accused infringing product. See *Markman v. Westview Instruments, Inc.*, 52 F.3d 967,

970-71 (Fed. Cir. 1995); *Cybor Corp. v. FAS Techs., Inc.*, 138 F.3d 1448, 1454 (Fed. Cir. 1998).

Scope of Claims

In a carefully considered and well written Markman ruling, United States District Judge Robert E. Payne, of the United States District Court for the Eastern District of Virginia, Richmond Division, held the following regarding construction of the '507 patent.

> Claims 2-5 of the '507 patent are construed as product-by-process claims. The '507 patent's disputed claim terms have the following definitions:
>
> > (1) "Crystalline" means "Crystal A;"
> >
> > (2) "shows" requires the display of a powder X-ray diffraction pattern which demonstrates the existence of the relevant peaks to a scientifically acceptable degree of certainty either visually or by other appropriate means of data display;
> >
> > (3) "peaks" is the plural of "peak;" a "peak" exists at a powder x-ray diffraction angle that corresponds to an intensity measurement greater than measurements attributable to

> "noise" if that angle is immediately preceded by and immediately followed by powder X-ray diffraction angle with a lower intensity measurement; "noise" refers to those portions of a PXRD pattern produced by intrinsic measurement error, and which cannot be associated with a scientifically significant quantity of the material which is the subject of the PXRD test;
>
> (4) "about" encompasses measurement errors inherently associated with powder X-ray diffraction testing.

Lupin, Ltd. v. Abbott Labs., 484 F. Supp. 2d 448 (E.D. Va. 2007). The parties have stipulated that Judge Payne's ruling shall be adopted by this court as its determination, as a matter of law with respect to this preliminary injunction proceeding, of the correct meaning and scope of the asserted claims. Therefore, this court hereby adopts Judge Payne's Markman ruling.

First we must resolve the parties' disagreement as to the correct interpretation of Judge Payne's ruling. Afterwards, we will analyze their arguments and evidence to determine whether the defendants' products in fact infringe the '507 patent. We will begin this analysis with a closer look at the actual '507 patent itself.

The '507 Patent

The first claim of the '507 patent construed by Judge Payne is the following:

> 1. Crystalline 7-[2-(2-aminothiazol-4-yl)-2-hydrox-yiminoacetamido]-3-vinyl-3-cephem.-4-carboxylic acid (syn isomer) which shows the peaks at the diffraction angles shown in the following table in its powder X-ray diffraction pattern:
>
> | diffraction angle ([degree]) |
> |---|
> | about 14.7 |
> | about 17.8 |
> | about 21.5 |
> | about 22.0 |
> | about 23.4 |
> | about 24.5 |
> | about 28.1 |

U.S. Patent No. 4,935,507 col. 16 11.12-28 (filed Aug. 8, 1998). Based on this first claim, Judge Payne ruled, and the parties agree, that the crystalline cefdinir described in Claim 1, and in fact in Claims 2-5 (not reproduced here) is "Crystal A." They do, however, disagree as to which forms of crystalline cefdinir fall within the definition of "Crystal A." The plaintiffs, predictably enough, maintain that the defendants' products, although different substances than the plaintiffs' cefdinir anhydrate product, are

included within the definition of Crystal A. Defendants, of course, disagree.

They also disagree as to how to interpret Judge Payne's ruling on "peaks" and "about." Finally, they disagree on how to construe "powder X-ray diffraction pattern" ("PXRD"), which was not discussed in Judge Payne's ruling. All three of these disagreements are critical to our final determination; therefore, we will examine them each in turn.

Crystal A

There is no more important aspect of this lawsuit than defining the scope of the '507 patent, which centers upon determining the definition of Crystal A as Judge Payne construed it. Our guiding principle in this determination comes from Judge Payne's decision, when he quoted the Federal Circuit. "[A]lthough the claims are not necessarily limited to the preferred embodiment of the invention, 'neither do the claims enlarge what is patented beyond what the inventor has described as the invention.'" *Lupin*, 484 F. Supp. 2d 448, quoting *Netword, LLC v. Centraal Corp.*, 242 F.3d 1347, 1352 (Fed. Cir. 2001). Judge Payne wrote that Claims 1-5 "define 'Crystal A' and, accordingly, one is justified in reading 'crystalline cefdinir' to mean 'Crystal A' throughout the claims." *Lupin*, 484 F. Supp. 2d 448. Plaintiffs seize on Judge Payne's follow up statement, that "the Court is not affirmatively defining Crystal A to be anything other than what the claims say it is." 484 F. Supp. 2d 448. The crux of their argument, however, arises out of Judge Payne's next statement:

> The claims explicitly define what Crystal A is, but only implicitly define what it is not. At this juncture, it is neither necessary nor appropriate to decide whether any known forms of cefdinir are necessarily excluded from the scope of the '507 patent's claims as a consequence of defining the '507 patent's invention to be Crystal A. The Court notes that . . . the '507 patent's specification quite clearly distinguishes the '507 patent's invention (Crystal A) from the forms of cefdinir disclosed in the '334 patent.

484 F. Supp. 2d 448. The plaintiffs focus on Judge Payne's statement, that "any subsequently discovered crystalline form of cefdinir that features the seven peaks in Claim 1 is, by definition, Crystal A, and not something else." 484 F. Supp. 2d 448. They conclude that, in order to prove infringement, they "are only required to demonstrate the presence of the seven peaks of claim 1, which define Crystal A, and not to show the peaks of claim 1 as that phrase is used in the claim." Pl. Reply Br. at 3. Defendants claim that the '507 patent contains no discussion or disclosure of a crystalline form of cefdinir other than "Crystal A, "and that their products are not Crystal A.

For the reasons explained below, we agree with defendants' interpretation of Judge Payne's construction of the '507 patent that the '507 patent is limited only to Crystal A as disclosed in the patent,

which does not include defendants' products within the claims set forth in the patent.

Show the peaks

Powder x-ray analysis of a crystalline substance enables scientists, and perhaps even judges, to identify the substances used in compounds. Judge Payne ruled that "a 'peak' exists at a powder x-ray diffraction angle that corresponds to an intensity measurement greater than measurements attributable to 'noise' if that angle is immediately preceded by and immediately followed by powder X-ray diffraction angle with a lower intensity measurement. . ." 484 F. Supp. 2d 448. Plaintiffs maintain that this is a strict definition, based on Judge Payne's statement that "any intensity requirement, whether absolute or relative, might unjustifiably limit the scope of the '507 patent to cover only the pure form of Crystal A." 484 F. Supp. 2d 448. Nothing in the patent, writes Judge Payne, indicates that Crystal A is claimed only in its pure form. 484 F. Supp. 2d 448. The plaintiffs maintain, as will be shown in the infringement analysis below, that, because Judge Payne appeared to reject the intensity requirement proposed by the plaintiff in *Lupin,* any peak which can be shown at the correct diffraction angle will suffice to satisfy the peak requirement in Claim 1. We believe, however, that this interpretation of Judge Payne's opinion is flawed and is rejected by Judge Payne's reasoning.

While it is true that, in the *Lupin* case, Judge Payne rejected plaintiff Lupin's argument that peaks referred only to the most intense features in the PXRD pattern and instead held that peaks referred

simply to powder x-ray diffraction angles that corresponded to an intensity measurement greater than measurements attributable to "noise" if that angle is immediately preceded by and immediately followed by powder X-ray diffraction angle with a lower intensity measurement, plaintiff's resulting interpretation of the definition misunderstands Judge Payne's reasoning.

Judge Payne notes that "the only 'peaks' listed in the '507 patent correspond with distinctive features of significant intensity, which, as indicated by Figure 1 [of the '507 patent], have obvious rises and falls before and after reaching a single apex." *Lupin*, 484 F. Supp. 2d 448. Although Claim 1 does not explicitly address intensity of peaks and Judge Payne did not explicitly "import" an intensity requirement into the claim, Judge Payne notes that the PXRD angles listed in Claim 1 correspond with the "most intense and pointed features in Figure 1 of the patent's specification" and "the charts displayed in columns 12 and 14 of the specification, which mathematically describe 'peaks,' list no peak smaller than eight percent of the tallest listed peak's intensity." *Id.*

Judge Payne's definition of peaks does contain a limiting feature, specifically "an intensity measurement greater than measurements attributable to "noise" if that angle is immediately preceded by and immediately followed by powder X-ray diffraction angle with a lower intensity measurement." Judge Payne did, however, explicitly reject peaks which were "nothing like the features displayed in Figure 1." Judge Payne continues to say that "[s]uch an interpretation of 'peaks' is nonsensical. Not only is it totally unrelated to the 'peaks' identified in the

specification, but it would fail to describe 'distinguishing' features at all." 484 F. Supp. 2d 448. He also notes that "the '507 patent simply does not support a reading of 'peaks' under which a 'peak' would exist at every point of measured intensity above the background noise, and nothing in the record indicates that person of ordinary skill in the art would accept such a definition of 'peaks.'" *Id.*

About

Judge Payne held that "'about' encompasses measurement errors inherently associated with powder X-ray diffraction testing." The parties disagree as to the measurement errors which comport with this holding. Plaintiffs maintain that the standard deviation is +/- .20 [degree]. Defendants maintain that the standard deviation is +/- .10 [degree]. Both sides presented experts who testified as to publications supporting one or the other methods, but ultimately we were persuaded by the defendants' expert, Dr. Alan Pinkerton, who asserted that the allowable variability in PXRD pattern peak position is +/- .10 [degree] a position supported by the U.S. PHARMACOPEIA XXI (1985).

The plaintiff's expert, Dr. Jerry Atwood, also referred to the U.S. PHARMACOPEIA, but interpreted the phrase "20 values should typically be reproducible to +/- .10 [degree] or 0.20 degrees," see *id.,* as indicating the correct standard measurement error is +/- .20 [degree]. We interpret the ".20 degrees" in this text as limiting the total variance plus and minus to .20 [degree] Dr. Atwood's conclusion could result in a measurement differentiation of as much as .40 [degree], a result we feel is inconsistent with the

U.S. PHARMACOPEIA. We therefore interpret Judge Payne's holding of a measurement error inherently associated with powder X-ray diffraction testing to be +/- .10 [degree].

Powder X-ray Diffraction Pattern

Claim I states that Crystal A shows the peaks at the diffraction angles in its powder X-ray diffraction pattern. Judge Payne did not construe the meaning of the term "powder X-ray diffraction" in his opinion. Plaintiffs contend that they will be able to demonstrate infringement by testing a single crystal using a [theta]/[theta] X-ray diffractometer and a synchroton which then calculates the PXRD pattern. Defendants claim that Claim 1 requires that the pattern must show the peaks using conventional powder x-ray diffraction. They also claim that because the '507 patent does not mention the synchroton, it cannot be used to demonstrate infringement. We disagree. A plain reading of Claim 1 does not use the word "conventional." The term "powder X-ray diffraction" is used a modifier for the word "pattern," one of the few terms not at issue in this case. Because we do not find that the '507 patent specifies one particular manner of producing a powder X-ray diffraction pattern, we reject defendants' argument that a single crystal diffraction which calculates a powder X-ray diffraction is disallowed.

Summary of Scope Analysis

We close our scope analysis of the '507 patent with the following conclusions, reaffirming once again our adoption of Judge Payne's April 27, 2007 Markman ruling. We find that (1) the '507 patent is

limited only to Crystal A as embodied in the patent; (2) while a "peak" exists at a powder x-ray diffraction angle that corresponds to an intensity measurement greater than measurements attributable to "noise" if that angle is immediately preceded by and immediately followed by powder X-ray diffraction angle with a lower intensity measurement, a peak does not exist at every point of measured intensity above the background noise; (3) the measurement error inherently associated with powder X-ray diffraction testing is +/- .10 [degree]; and (4) the '507 patent does not specify one particular manner of producing a powder X-ray diffraction pattern.

Infringement

We must now determine whether the plaintiffs are likely to be able to prove that the defendants have in fact infringed the '507 patent by comparing the properly construed claims to the accused infringing products. For a product literally to infringe a patent claim, every limitation recited in a properly construed claim must be exactly present in the accused product. *Cole v. Kimberly-Clark Corp.*, 102 F.3d 524, 532 (Fed. Cir. 1998). Infringement may also be established under the doctrine of equivalents. *Warner-Jenkinson Co., Inc. v. Hilton Davis Chem. Co.*, 520 U.S. 17, 35, 117 S. Ct. 1040, 137 L. Ed. 2d 146 (1997). In order to establish infringement under the doctrine of equivalents, there must be a showing that the difference between the patent and the accused product perform "the substantially same function in substantially the same way with substantially the same result as each claim limitation of the

patent." *AquaTex Indus., Inc. v. Techniche Solutions*, 479 F.3d 1320, 1326 (Fed. Cir. 2007).

Accordingly, we will examine whether cefdinir monohydrate infringes the '507 patent. We will also examine whether the defendants' cefdinir monohydrate contains within it any cefdinir anhydrate. Finally, we will examine whether the defendants' cefdinir monohydrate is equivalent to cefdinir anhydrate under the doctrine of equivalents. In order to make these determinations, we begin by turning once again to the requirements of Claim 1.

Claim 1 requires that, in order to characterize a crystalline structure as Crystal A or an accused product as infringing Crystal A, plaintiffs must show the peaks at seven diffraction angles in its powder X-ray diffraction pattern: about 14.7, about 17.8, about 21.5, about 22.0, about 23.4, about 24.5, about 28.1. We have already held that "about" means +/- .10 [degree], so our analysis for each diffraction angle will be limited to +/- .10 [degree].

We begin our analysis by considering plaintiffs' claim of literal infringement.

Literal Infringement

Plaintiffs advance two arguments to support their claim of literal infringement. First, they claim that the defendants' respective cefdinir products infringe the '507 patent because they contain cefdinir monohydrate, which shows the seven peaks in claim 1 and is obtainable by any of the processes of claims 2 through 4. Second, they claim that the defendants' respective cefdinir products infringe the '507 patent because they contain cefdinir anhydrate, which

shows the seven peaks in claim 1 and is obtainable by any of the processes of claims 2 through 5. As we have already established above, defendants' acknowledge that their products are in fact comprised in large or total part of cefdinir monohydrate, which they claim is not covered by the '507 patent, but which they claim is covered instead by the '334 patent, which expires on May 6, 2007. Additionally, defendants' claim that their products do not contain cefdinir anhydrate and that any of the shown peaks in common with their products and cefdinir anhydrate are due to the characteristics of cefdinir monohydrate.

The obvious place to start is to ask whether cefdinir monohydrate does in fact meet each of the peaks required in Claim 1. Plaintiffs claim that cefdinir monohydrate infringes because it shows the peaks in Claim 1, and thereby accords with Judge Payne's statement that "any form of crystalline cefdinir which displays peaks at the seven diffraction angles listed in Claim 1 is 'distinguished' as Crystal A." In response to the court's questions, plaintiffs' expert, Dr. Atwood, agreed that there were crystalline substances which were not covered by the '507 patent. Hearing Tr. 129. The defendants point directly to another crystalline substance, "Crystal B," which they claim (1) is their product, cefdinir monohydrate, (2) is described in the Japanese '199 patent, and (3) is covered by the '334 patent, specifically example 16.

To allege the infringement, the plaintiffs rely on an interpretation of Judge Payne's analysis that we have rejected in this opinion, that a peak exists at every point of measured intensity above the back-

ground noise. Plaintiffs used SCXRD analysis to calculate a powder X-ray diffraction pattern and found peaks which they claimed matched all seven peaks listed in Claim 1. They demonstrated through the use of visual charts the peaks which they claim matched the diffraction angles listed in Claim 1.

Dr. Atwood claims that for each peak listed in Claim 1, there was a corresponding peak in the PXRD pattern for cefdinir monohydrate, and listed them as follows: 14.84, 17.83, 21.33, 21.98, 23.53, 24.58, and 28.09. Only four of these seven peaks are within the +/- .10 [degree] that we have allowed as the definition for "about" in Claim 1. On that basis alone, the plaintiffs' claim of literal infringement fails, because in order for there to be literal infringement, each and every limitation of the claim must be met. But there are three more reasons.

First, while the diffraction angles listed above imply a story of closely related peaks, the visuals shown in the plaintiffs' exhibits and at the hearing tell an entirely different story, which is that cefdinir monohydrate is a *different substance* than cefdinir anhydrate. When the PXRD patterns for both substances are placed next to one another, they simply do not match. The seven peaks described in the '507 patent are tall and dramatically distinguished from the remainder of the PXRD pattern. Similarly, the PXRD for cefdinir monohydrate shows tall and dramatically distinguishing peaks. None of these prominent peaks for the cefdinir anhydrate match the ones for the cefdinir monohydrate. Dr. Atwood admitted as much when he said "by comparing the entire pattern for each form, it is clear that cefdinir 'Crystal A' and crystalline cefdinir monohydrate are

different crystal forms." While plaintiffs are understandably eager to interpret the '507 patent to include cefdinir monohydrate, we believe they are simply so different that they undermine the claims of literal infringement.

Second, in order to demonstrate infringement, the plaintiffs used a mathematical procedure called pseudo-Voigt fitting, which is used to determine accurately the size and position of smaller peaks which are partially overlapped by larger neighboring peaks. The resulting peaks "exist" but are "nothing like the features displayed in Figure 1. Indeed, [they] eviscerate" any of the descriptive value of the word peaks in the '507 patent. Indeed, the "peaks" were peaks only when interpreting Judge Payne's opinion in the awkward manner with which we disagree.

Third, the evidence does not convince us that there in fact are trace amounts of cefdinir anhydrate contained within the cefdinir monohydrate in defendants' products. Moreover, there is no evidence that, even if there were traces, that those trace amounts could be a contributing factor in the efficacy of the defendants' products. If there is a small amount of cefdinir anhydrate in defendants' products, we do not conclude that this could cause literal infringement of the '507 patent.

Finally, we heard persuasive evidence identifying the defendants cefdinir monohydrate as Crystal B. PXRD patterns of the defendants cefdinir monohydrate were superimposed on PXRD patterns of Crystal B; they matched in peaks and intensity. Further, defendants argued, and plaintiffs did not rebut, that

the reason that plaintiffs left reference to Crystal B out of the '507 patent was because Crystal B was contained within Example 16 of the '334 patent. Had Crystal B been included in the '507 patent application, the patent would not have issued because Crystal B had already been disclosed. We know that Crystal B was known to the plaintiffs because it had been included in the Japanese '199 patent. Thus we conclude that the plaintiffs deliberately excluded from the definition of Crystal A, cefdinir monohydrate, which is Crystal B.

Doctrine of Equivalents

Plaintiffs claim that the defendants' respective cefdinir products infringe the '507 patent under the doctrine of equivalents. They assert that Dr. Atwood's testimony about the similarity of shelf life, dissolution rate and bioavailability between cefdinir monohydrate and cefdinir anhydrate show conclusively that defendants' products infringe claims 1-5 of the '507 patent under the doctrine of equivalents. Under cross-examination, however, Dr. Atwood failed to establish that he had supported his opinion with empirical or substantive evidence. While an expert may offer an opinion on infringement, we need not credit unsupported conclusions. *See Rohm & Haas Co. v. Brotech Corp.*, 127 F.3d 1089, 1092 (Fed. Cir.1997) ("Nothing in the rules or in our jurisprudence requires the fact finder to credit the unsupported assertions of an expert witness").

Plaintiffs make the second argument that defendants' assertion to the FDA that their products were bioequivalent to cefdinir anhydrate in their ANDAs is an admission that they were infringing the '507

patent under the doctrine of equivalents. We disagree with this position. See *Upjohn Co. v. Mova Pharm. Corp.*, 31 F.Supp.2d 211, 215 n.2 (D.P.R. 1998) ("[An] admission of bioequivalence is not an admission of infringement under the doctrine of equivalents. They are two distinct concepts.") If bioequivalency meant per se infringement, no alternative to a patented medicine could ever be offered to the public during the life of a patent.

CONCLUSION

The plaintiffs have failed to persuade the court they are likely to be able to prove that defendants have literally infringed on the '507 patent and failed to show that defendants have infringed using the doctrine of equivalents. Moreover, they have failed to establish that defendants' products contain amounts of cefdinir anhydrate, if any, to cause infringement on the '507 patent. Because we have found that the plaintiffs have not shown that they are reasonably likely to succeed on the merits, there is no need for us to analyze the remainder of the factors required for the granting of a preliminary injunction. See *Polymer Technologies, Inc. v. Bridwell*, 103 F.3d 970, 973-974 (Fed. Cir. 1996); *Payless Shoesource Inc. v. Reebok Int'l Ltd.*, 998 F.2d 985, 988 (Fed. Cir. 1993). The defendants have successfully raised a substantial question concerning infringement, and therefore, the preliminary injunction should not issue.

For all the foregoing reasons, the plaintiffs' motion for a preliminary injunction [65] is denied.

It is so ordered.

Wayne R. Andersen

District Judge

Dated: May 3, 2007